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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/801,510      | 03/16/2004  | Frank Hossner        | P32145C1            | 3194             |

7590 03/21/2005

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EXAMINER

HABTE, KAHSAY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1624

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/801,510

Applicant(s)

HOSSNER ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 3 is/are rejected.
- 7) ☒ Claim(s) 1 and 4-6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-9 are pending in this application.

#### ***Election/Restriction***

2. Applicant's election of Group I without effective traverse in the reply filed on 3/4/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Specification***

3. The specification needs to be amended. According to MPEP 201.11, when a non-provisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 35 USC 120, a statement such as, "This application is a continuation of 09/787,980, filed 04/18/2002 "now abandoned" which is a 371 of PCT/EP99/06780, filed 09/14/1999" should appear as the first sentence of the specification.
4. The specification is objected, because the chemical structure in page 1 of the specification is not drawn properly. The bonds are not connected well in the tricyclic ring, e.g. double bonds of the phenyl ring at the bridge, the N is not connected to the C at 4-position of the 1,3-oxazine ring.

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### ***Abstract***

5. The abstract of the disclosure submitted on 3/16/2004 is the first page of the WIPO document (i.e. WO 00/17207). It is recommended that applicants submit the abstract in a separate sheet of paper as it was done in the parent case 09/787,980.

### ***Objection***

6. Claim 1 and claims dependent therefrom are objected because there is no period after the chemical structure. A claim should end in a period.

7. Claim 6 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note that the phrase "for use" is a mental step and it does not narrow down the limitations of claim 1. If applicants intend a method claim, the claim should be written in a method claim language.

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claims 2-3, the phrase "compound of formula (I) and its pharmaceutically acceptable salts" is not clear. Do applicants intend the compound and the pharmaceutical salt (i.e. a mixture) or do applicants intend to claim the compound of formula (I) or its salt separately? Note that claim 1 embraces the compound or the pharmaceutically acceptable salt, not both. If applicants intend "compound of formula (I), or its pharmaceutically acceptable salts", then claims 2-3 are duplicates of claim 1.

b. In claim 3, the phrase "compound of formula (I) and its pharmaceutically acceptable salts as claimed in claim 1 or claim 2 in synthetic form" is not clear. Note that claims 1-2 are drawn to compounds of formula (I) or a pharmaceutically acceptable salt thereof that are made by synthetic methods described on pages 8-12 of the specification. Since claims 1-2 are not drawn to natural products that are unpatentable, it is unclear what "synthetic form" are applicants referring.

#### ***Closest Prior Art***

9. The closest prior art is Gaster et al. (WO 9318036), but it fails to teach the 3-hydroxy on the butyl groups that is attached to N or the piperidinyI group.

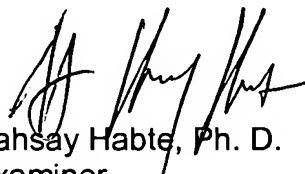
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**Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624

KH  
March 16, 2005